K120906 1/3

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

AUG 2 4 2012

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Rebecca Dill Specialist, Regulatory Affairs Telephone: (574) 372-4260 Fax: (574) 372-4605
Date:	August 21, 2012
Trade Name:	*Zimmer® Trabecular Metal™* Total Ankle
Product Code / Device:	HSN – Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer
Regulation Number / Description:	21 CFR § 888.3110 - Ankle Joint metal/polymer semi-constrained cemented prosthesis
Predicate Device:	Alvine Total Ankle Prosthesis (Agility), manufactured by Depuy Orthopaedics, Inc., K920802, cleared December 17, 1992 and K020541, cleared May 20, 2002. Salto Talaris Total Ankle Prosthesis, manufactured by Tornier Inc., K060544, cleared November 13, 2006.
Device Description:	The *Zimmer Trabecular Metal* Total Ankle is an implant and instrument system designed to preserve motion in arthritic ankle patients. It is a semi-constrained device intended for the replacement of the articulating surfaces of the ankle that have been affected by a disease state or injury. The *Zimmer Trabecular Metal* Total Ankle is a bicondylar system. The articular surfaces of the implants are designed to mimic the truncated cone

shape of the natural ankle joint, thereby reproducing normal ankle joint kinematics.

The talar component is machined from a wrought Cobalt Chrome Molybdenum (CoCrMo) Alloy (*Zimaloy®*) diffusion bonded to a *Trabecular Metal*™ surface via an interlayer of commercially pure Titanium.

The tibial component consists of a *Tivanium®* (Ti-6Al-4V) tibial baseplate diffusion bonded to a *Trabecular Metal*™ surface and a modular insert of *Prolong®* Highly Crosslinked Polyethylene (HXLPE).

Intended Use:

Total ankle arthroplasty is intended to provide a patient with limited mobility by restoring alignment, reducing pain and preserving the flexion/extension movement within the ankle joint.

The *Zimmer Trabecular Metal* Total Ankle is indicated as a total ankle replacement in primary or revision surgery for patients with:

- Rheumatoid arthritis.
- Post-traumatic arthritis.
- Degenerative arthritis.

This device is intended for cemented use only.

Comparison to Predicate Device:

The substantial equivalence of the *Zimmer Trabecular Metal* Total Ankle to the Alvine Total Ankle Prosthesis (Agility) and the Salto Talaris Total Ankle Prosthesis is demonstrated by its similarity in indications for use, design, materials, sterilization method, classification name and materials used.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The following non-clinical testing was performed.
1. Testing per FDA's guidance document

"Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone Or Bone Cement".

2. Testing per ASTM F2665 "Standard Specification for Total Ankle Replacement Prosthesis".

3. MRI compatibility testing for tibial and talar components.

4. Range of Motion of the Zimmer Trabecular Metal Total Ankle.

5. Fatigue Analysis of the Cemented Zimmer Trabecular Metal Modular Total Ankle Replacement System.

6. Wear Evaluation of the Zimmer Trabecular Metal Modular Total Ankle Replacement System.

7. Zimmer Trabecular Metal Modular Total Ankle Replacement System Contact Area / Contact Stress Evaluation.

8. Zimmer Trabecular Metal Modular Total Ankle System Constraint Evaluation

Non-clinical testing demonstrated that this device met performance requirements and is as safe and effective as the predicate device.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 24 2012

Zimmer, Inc.
% Ms. Rebecca Dill
P.O. Box 708
Warsaw, IN 46581

Re: K120906
Trade/Device Name: Zimmer Trabecular Metal Total Ankle
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HSN
Dated: August 15, 2012
Received: August 16, 2012

Dear Ms. Dill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120906

Device Name:

Zimmer® *Trabecular Metal*™ Total Ankle

Indications for Use:

Total ankle arthroplasty is intended to provide a patient with limited mobility by restoring alignment, reducing pain and preserving the flexion/extension movement within the ankle joint.

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- Degenerative arthritis.

This device is intended for cemented use only.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120906